

Message Text

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ORIGIN HEW-04

INFO OCT-01 ARA-10 EUR-12 EA-10 ISO-00 OES-04 EB-06 COME-00

RSC-01 /048 R

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DRAFTED BY DHEW/FDA/JRWEINROTH MD

APPROVED BY OES/SCI/BMP:PHEMILY

DHEW/OIH:MACODDING

EA/J:CDUNKERLY

EUR/CE:SGEORGE

ARA/MEX:JRHAMILTON

OES/SCI/BMP:MBEAUBIEN

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R 311805Z OCT 74

FM SECSTATE WASHDC

TO AMEMBASSY BONN

AMEMBASSY TOKYO

AMEMBASSY MEXICO

UNCLAS STATE 239439

E.O.11652:NA

TAGS: ETRD EIND TBIO GW JA MX

SUBJECT: RECALL OF AUSRIA 125 DIAGNOSTIC KIT - LABEL MIXUP

1. FDA ADVISES THAT ABBOTT LABORATORIES, INC., NORTH CHICAGO, ILLINOIS, 60064 IS RECALLING THE FOLLOWING PRODUCT: "LIST NO. 6714 HEPATITIS ASSOCIATED ANTIBODY (ANTI-AUSTRALIA ANTIGEN) 125 I (GUINEA PIG) AUSRIA 125 DIAGNOSTIC KIT". THE PRODUCT IS A RADIO-IMMUNOASSAY FOR THE DETECTION OF HEPATITIS ASSOCIATED ANTIGEN. THE KIT CONSISTS OF 50 TUBES XXX ONE VIAL (10 ML.) HEPATITIS ASSOCIATED ANTIBODY (ANTI-AUSTRALIA ANTIGEN) 125 I APPROXIMATELY 8 MICRON PER BOTTLE XXX ONE VIAL (5 ML.) NEGATIVE CONTROL XXX ONE VIAL 7 ML.) TRIS XXX ONE VIAL (3 ML.) POSITIVE CONTROL XXX FOR IN VITRO DIAGNOSTIC USE. THE KITS WERE ALSO PACKAGED IN 100'S (ONE VIAL OF HAA) AND 1,000'S (10 VIALS OF HAA) WITH EXPIRATION DATE AND MASTER LOT NUMBER ON THE KIT LABELS. THE LABEL OF THE 10 ML. VIAL OF HAA IS IDENTIFIED
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IN PART WITH THE LIST NUMBER "8334" AND "(GUINEA PIG)" AND

EXPIRATION DATE AND LOT NUMBER. SOME VIALS OF HAA WERE
ERRONEOUSLY LABELLED WITH LABEL FOR LIST NUMBER "8809"
"HUMAN".

3. LOT NUMBERS AS FOLLOWS:

LIST 6714: AA 748, AA 750, AA 757 - 1,000'S ARE INDICATED
BY SUFFIX M, 50'S BY SUFFIX L, EXPIRATION DATE 7/21/74.
LIST 8334: HA 374, EXPIRATION DATE 7/21/74. KITS CON-
TAINING VIALS MISLABELED AS LIST 8809 WERE IDENTIFIED
WITH THE SAME LOT NUMBER AND EXPIRATION DATE.

4.. THE PRODUCT HAS EXPIRED. CUSTOMERS RECEIVING THE MIS-
LABELED VIALS OF HAA WERE INSTRUCTED TO DESTROY THEM. ALL LOTS
WERE SHIPPED ON 7/18 AND 7/19/74.

5. THE FOLLOWING EXPORT SHIPMENTS WERE MADE TO:

1. ABBOTT GMBH DIAGNOSTICS DIVISION, 6236 ESCHBORN, WEST
GERMANY, INVOICE 96F985, 5X50 LOT AA750; INVOICE 96F986,
8X1,000, 120X100 LOT AA 748 OR 750M.

2. DAINABOT - JAPAN, INVOICE 96F993 50X100, LOT AA748.

3. LABORATORIA DE DILUCION, COMISION NACIONAL DE ENERGIA
NUCLEAR, MIGUEL ANGEL DE QUEVEDEO NO. 530-A, MEXICO 21
D.F., MEXICO INVOICE 16G014 3X100, LOT HA748.

6. POSTS ARE REQUESTED TO DETERMINE IF CONSIGNEES ARE FAMILIAR
WITH DETAILS OF RECALL AND TO INFORM THEM THAT ABBOTT RECOM-
MENDED THAT CUSTOMERS RECEIVING MISLABELED VIALS WERE ADVISED
TO DESTROY KITS CONTAINING THEM, AND REQUEST REPLACEMENTS.
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Message Attributes

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Decaption Note:
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Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
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Disposition Event:
Disposition History: n/a
Disposition Reason:
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30 JUN 2005

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TAGS: ETRD, EIND, TBIO, GE, JA, MX, ABBOTT LABORATORIES
To: BONN MEXICO
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